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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/943,144	10/03/1997	TOMOKAZU KOSHIBA	21850208P-SP	9009

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/943,144

Applicant(s)

KOSHIBA, TOMOKAZU

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 18-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-33 is/are allowed.
- 6) ☒ Claim(s) 18-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Rejection of Claims 18, 20-22, and 25-28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's amendments and arguments.
2. Claims 18-30 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of records set forth in the office action mailed 8/4/99, 4/25/00, 6/7/01, 6/4/02 and as stated below. Applicant's arguments filed 12/4/02 have been fully reconsidered but are not deemed persuasive.

Applicant asserts that by claiming a gene of about 4.4kbp, a finite number of polynucleotide sequences now fit within the scope of Claim 18, that every conceivable nucleotide structure can be envisaged quite simply because every 'envisaged' polynucleotide sequence can be tested for the prescribed aldehyde oxidase activity. Applicant further asserts that although the enumerated primers would amplify genes from outside the scope of the claim the test for aldehyde oxidase activity would eliminate them from consideration (response pages 9-10).

Function alone cannot distinguish members of a genus and recitation of what a gene does or how to isolate a gene is not an adequate description of that gene because it does not describe what the gene is. A precise description of the defining structural elements, of the claimed genus of nucleic acids, is required to demonstrate that Applicant is indeed in possession of the claimed invention. Although, Applicant describes the nucleotide sequence for oligonucleotides used in PCR to isolate SEQ ID NO: 1 and 3 encoding SEQ ID NO: 2 and 4 from maize, Applicant does not describe the composition or the structure of any of the other broadly claimed non-exemplified genes from across all phyla or species, other than maize, encoding enzymes of the claimed invention. Since Applicant does not adequately describe the composition of said genes, the methods of controlling aldehyde oxidase production in a transformed host cell of Claims 28-30 are not adequately described as well.

3. Claims 18-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated nucleic acids of SEQ ID NO: 1 and SEQ ID NO: 3 encoding aldehyde oxidase, does not reasonably provide enablement for any aldehyde oxidase nucleotide sequence from any plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is repeated for the reasons of records set forth in the office action mailed 8/4/99, 4/25/00, 6/7/01, 6/4/02 and as stated below. Applicant's arguments filed 12/4/02 have been fully reconsidered but are not deemed persuasive.

This rejection has been modified to broaden the scope of enablement to include SEQ ID NO: 3 in view of Applicant's amendment of the claims to recite "about 4.4 Kbp." It is conceded that SEQ ID NO: 3 is just about 4.4 Kbp.

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Applicant asserts that the Examiner has failed to make a *prima facie* case as to why the claims lack enablement. Applicant further asserts that even if this case had been made Applicant has provided two examples that work and that undue experimentation is not required to practice the invention because the experimentation required is only routine (response pages 10-12).

Applicant has not addressed examiners arguments concerning the unpredictable nature of PCR amplification using DNA primers that diverge with respect to sequence identity, a situation that would arise given the lack of teaching in the specification for PCR isolation of a broad range of aldehyde oxidase genes, and the unpredictable nature of modifying gene expression when no phenotype is taught. Furthermore, since Applicant has not enabled the nucleic acids throughout the scope of the claims, the methods of controlling aldehyde oxidase production in a transformed host cell of Claims 28-30 are likewise not enabled.

4. Claims 31-33 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.  
February 19, 2003



AMY J. NELSON, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600